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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,466	03/07/2002	David A. Brown	AGI-127	4676

7590

10/08/2003

Maurice M Klee
Attorney at Law
1951 Burr Street
Fairfield, CT 06430

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,466

Applicant(s)

BROWN ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-10, 12-20, 29-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 12-20 and 29-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-7, 9-10, 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the word "such" is confusing as to whether the limitation following the word is part of the claimed invention. Amending the claim to recite "said" will overcome this rejection.

In claim 12 the phrase "that includes" is confusing as to whether the limitation following the phrase is part of the claimed invention. Amending the phrase to recite "comprising" will overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-10, 12-20, 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,723,179 (Granger) in view of CA123:208694 (Claassen) and WPIDS 1996-131194 (Fontanel).

Granger (columns 1-2, column 3-line 28, column 4, lines 10-11, column 10) discloses a composition comprising ursolic acid and a retinoid and optionally another active ingredient and a method of using it to treat various skin conditions including

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atopic dermatosis, photodamaged, dry and aged skin. Granger further discloses that the composition increases keratinocytes. The instant claims differ over Granger in reciting an increase in the lipid content of the keratinocytes and that the ursolic acid be encapsulated in liposomes comprising phospholipid bilayer membranes. Dependent claims recite treatment of ichthyosis or ichthyosoform dermatoses, amount of ursolic acid, addition of a steroid compound, types of lipids and employing potassium sorbate preservative.

However, it would be obvious to use encapsulate ursolic acid in liposomes which have phospholipid bilayer membranes, since Fontanel discloses compositions which employ liposomes comprising ursolic acid and Classen discloses that liposomes have phospholipid bilayer membranes. Moreover, it would be obvious that if ursolic acid increases keratinocytes, the amount of lipid content and the specific lipids would increase. It would also be obvious to one of ordinary skill in the art that compounds known to be useful to treat atopic dermatosis would be effective at treating ichthyosis or ichthyosoform dermatoses. It would additionally be obvious to include a steroid in the composition, since anti-inflammatory steroids such as hydrocortisone are routinely employed in dermatological compositions. Additionally, potassium sorbate preservative is routinely employed in the composition art. Furthermore, once the use of a compound is known it is within the skill of the artisan to determine the optimum amount to use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/614

September 30, 2003